DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Signostics Limited
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

January 14, 2015

Re: K143493
Trade/Device Name: SignosRT Bladder
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO ITX
Dated: December 28, 2014
Received: January 7, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143493

Device Name

SignosRT Bladder

Indications for Use *(Describe)*

SignosRT Bladder scanner projects ultrasound energy through the lower abdomen of a patient to obtain an image of the bladder that is used to non-invasively determine bladder volume. Users must have ultrasound training before using the device.

Contraindications

The SignosRT Bladder Scanner is designed for percutaneous scanning only. Do not attempt intracavity imaging; in particular, trans-esophageal, trans-vaginal and trans-rectal scans are contraindicated.

The SignosRT Bladder Scanner is contraindicated for pregnant patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Indications for Use Form

TABLE 1 - SIGNOSRT BLADDER INDICATIONS FOR USE FORM

System: SignosRT Bladder
Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

TABLE 2 - SIGNOSRT BLADDER SCANNER INDICATIONS FOR USE FORM

System: SignosRT Bladder

Transducer: S3 (P03479)

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

1. **Sponsor:**
   Signostics Ltd
   PO Box 1048, Pasadena
   1284 South Road
   Clovelly Park, SA 5042
   Australia

2. **Contact Person:**
   Stewart Bartlett
   Quality and Regulatory Manager
   Telephone: +61 (8) 7424 0600

3. **Date Prepared:**
   December 28, 2014

4. **Device Name:**
   SignosRT Bladder

5. **Proprietary/Marketed Names:**
   SignosRT Bladder

6. **Common/Usual Name:**

   Diagnostic ultrasound system and transducer

7. **Classification**

   Regulatory Class: II

   Review Category: Tier II

Ultrasonic Pulsed Echo Imaging System	(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasound Transducer	(21 CFR 892.1570, 90-ITX)

   Classification Panel: Radiology

8. **Predicate Devices**

   Portascan Bladder Scanner (K033906)

   SignosRT Ultrasound System (K130659)

9. Risk Analysis Method Used

Signostics Ltd applied ISO-14971 to the design and development of the SignosRT Bladder. The conclusion from the risk analysis was the device was safe for its intended use and does not pose any unacceptable risks.

10. Basis for Substantial Equivalence – Technological Characteristics

Signostics Ltd believes the SignosRT Bladder described in this Submission is substantially equivalent to the predicate devices as follows:

a. Portascan Bladder Scanner (K033906)

b. SignosRT Ultrasound System (K130659)

The SignosRT Bladder is substantially equivalent to the predicate devices listed above. All systems transmit ultrasonic energy into patients, then process received echoes to produce on-screen images of anatomy. All systems allow for B-mode imaging and measurements of volume of a bladder. The indication for use statement of the SignosRT Bladder is identical to the Portascan. The SignosRT Personal Ultrasound system (K130659) is a general ultrasound imaging device with an intended use statement covering a number of areas, including the abdomen which includes the bladder.

All systems enable an estimated bladder volume to be calculated from a single scan or from two scans for more accurate results. The algorithms used to calculate bladder volume are identical for the SignosRT Bladder and the predicate SpeqRT Personal Ultrasound System.

The SignosRT Bladder is identical in construction, materials, and controls to the SignosRT Personal Ultrasound (K130659), with the only difference being the indications for use statement and the software configuration. The patient contact materials are identical. The transducer and operating frequency (3.5MHz) are also identical. Both systems contain sector transducers with annular (circular) acoustic elements generating pie shaped images, have identical operating frequency, identical outer diameter of acoustic crystal, identical acoustic output, and both maintain MI and TI to be <1.0 at all times.

The predicate SignosRT Personal Ultrasound has a remote display mode to allow streaming of the video to a larger display. The SignosRT Bladder also has support to allow streaming of the video to a larger display.

The predicate Portascan has printer as part of the device. The SignosRT Bladder scanner and predicate SignosRT Ultrasound System both can be connected directly to a USB PictBridge printer for full-size printouts, or transfer images to a PC running SigViewer accessory software to print images.

11. Device Description

The Signostics Ltd SignosRT Bladder is a hand-held, diagnostic ultrasound system with an on-screen display. Its purpose is to acquire ultrasound echo data and display it in B-Mode on an LCD display to enable non-invasive volume measurement of a patients bladder.

Technical specifications for the Signostics SignosRT Bladder are as follows:

System				
Transducer frequencies:	3MHz (S3 transducer)			
Frame rate:	8Fps or 16Fps (Imaging only)			
Ultrasound lines/frame:	128 lines for 90º frame at 10cm			
Fields of View:	1-18 cm for 3MHz			
External Video Output:	No			
Liquid-Crystal Display:	18 bit, 262,000 Color, Active Matrix TFT LCD			
Materials	Sabic Cycoloy HC1204HF, Mitsui TPX-MED18, Sabic Versollen OMX1255NX-1			
Size: -				
Width:	6.8 cm			
Height:	11.5 cm			
Depth:	2.0 cm			
Weight:	0.13 kg			
Electrical				
External Power:	Input:	100-240 VAC, 50-60Hz	Output:	5 VDC @ 2A
Battery:	Li-Ion battery pack (2 Whr)			
Leakage Current:	10 μA maximum			
Primary Breakdown Voltage:		3000VAC		
Safety Standards:	IEC 60601-1:2005, ES60601-1:2005, IEC 60601-2-37:2007, IEC 60601-1-2:2007, ISO 10993-1:2003			
Protection Class:	Class II: per IEC 60601-1			
Degree of Protection:		Type BF: per IEC 60601-1		

Environmental	
Mechanical Shock:	Drop and push testing per ES60601-1
Mechanical Vibration:	Random Acceleration Profile per JIS Z 0232:2004 5Hz-300Hz
Drop Test (to concrete):	1 meter
Operating Temperature:	0 to 40 C
Humidity:	20 to 80% RH, non-condensing
Water Resistance:	Transducer IPX7 lens, IPX1 probe degree of protection against water
Altitude:	0.7 – 1.05 standard atmospheres (2500m or 8200 feet) operating
Storage	
Temperature:	-20 to 45 C
Humidity:	10 to 90% RH, non-condensing
Altitude:	0.5 – 1.05 standard atmospheres storage

12. Non-clinical Performance Data

The SignosRT Bladder has been bench tested for imaging performance and measurement accuracy, with tests showing the SignosRT Bladder imaging performance and measurement accuracy to be substantially equivalent to the predicate devices. The measured lateral and axial resolution for the SignosRT Bladder is identical to the predicate SpeqRT Personal Ultrasound System. The measured volume accuracy on a phantom was a maximum of +-9.6%, well within the specified +-15%.

The SignosRT Bladder Scanner device has been tested by independent laboratories to IEC 60601-1:2005, IEC 60601-2-37:2007, IEC 60601-1-2:2007, ISO 10993-5:2009, ISO 10993-10:2002, ISO 10993-10:2010, ISO 10993-12:2007, NEMA UD-2-2004 (R2009), NEMA UD-3-2004(R2009) and found to comply with all standards.

The software and firmware in the SignosRT Bladder has been developed and verified according to IEC 62304:2006. The verification reports (Appendix R and V), traceability (Appendix Q), and risk analysis (Appendix A) demonstrate the SignosRT Bladder operates as intended and risks mitigated in firmware have been verified.

The conclusion from the testing is the device is safe and effective for its intended use, and performs as well or better than the predicate devices.